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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ANISA HEMMITT and MICHAEL HEMMITT, ***Plaintiffs,*** **v.** **BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., BERLEX, INC., BAYER SCHERING PHARMA AG, BAYER AG, JANE DOE DISTRIBUTORS (1-50), JILL DOE MANUFACTURERS (1-50), JACK DOE WHOLESALERS (1-50), JAKE DOE SELLERS (1-50), JOHN DOE MARKETERS (1-50), JOAN DOE FORMULATORS (1-50), JIM DOE HEALTH CARE PROVIDERS (1-50), JEAN DOE (1-50),** ***Defendants.***	**Civil Action No. _____** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs, by and through counsel, and for their Complaint against Defendants, allege as follows:

I. THE PARTIES

1. Plaintiff Anisa Hemmitt ("Plaintiff") resides in Arkansas.

2. Plaintiff Michael Hemmitt resides in Arkansas. At all times relevant, Michael Hemmitt was married to Plaintiff Anisa Hemmitt.

3. Plaintiff Anisa Hemmitt was prescribed and ingested Yaz® and suffered injury, including, but not limited to, removal of her gallbladder.

4. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

5. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

6. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

7. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

8. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

9. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

10. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

11. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of the approved New Drug Application ("NDA") for Yaz®.

12. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of the approved New Drug Application ("NDA") for Yasmin®.

13. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

14. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

15. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

16. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.

17. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

18. Defendant BAYER SCHERING PHARMA AG'S headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

19. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin®.

20. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yaz®.

21. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

22. Defendant BAYER AG is the third largest pharmaceutical company in the world.

23. Defendant BAYER AG is the parent/holding company of all other named Defendants.

24. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

25. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG, shall be referred to herein individually by name or jointly as "Defendants."

26. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

27. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

28. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive Yaz®.

29. JANE DOE DISTRIBUTORS (1-50), JILL DOE MANUFACTURERS (1-50), JACK DOE WHOLESALERS (1-50), JAKE DOE SELLERS (1-50), JOHN DOE MARKETERS (1-50), JOAN DOE FORMULATORS (1-50), JIM DOE HEALTH CARE PROVIDERS (1-50), and JEAN DOE (1-50), are corporations, partnerships, companies, or other entities involved in the marketing, design, development, manufacture, production, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution or release of Yasmin®, whose identities are not presently known by Plaintiff.

II. JURISDICTION AND VENUE

30. Jurisdiction and venue are proper under the United States Constitution as well as under New Jersey law regarding personal jurisdiction. Defendants have transacted substantial and continuous business in the State of New Jersey, and have committed tortious acts and deceptive practices and breached warranties in this state, which form the basis for this cause of action.

31. This Court has jurisdiction over this matter pursuant to 28 U.S.C. Section 1332, for diversity of citizenship, and Plaintiff claims an amount in controversy exceeding $75,000.00.

32. The applicable statute of limitations is tolled based on Defendant's fraudulent concealment of the dangers and adverse side effects of the drug Yaz® from Plaintiff as stated more fully herein. Additionally, for the reasons stated herein, Defendants are equitably estopped from raising the statute of limitations defense.

III. FACTUAL ALLEGATIONS

A. Nature of the Case

33. Plaintiff brings this case against Defendants for damages associated with Plaintiff's ingestion of the pharmaceutical drug Yaz® (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered various injuries, serious physical pain and suffering, medical, hospital and surgical expenses, and loss of consortium as a direct result of Plaintiff's use of Yaz®.

B. Yasmin® and Yaz® Contain a "Fourth Generation" Progestin

34. Yaz® and Yasmin® are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

35. Yasmin® received FDA approval first in 2001. It is a combination of drospirenone, a progestin, and ethinyl estradiol, an estrogen.

36. Each tablet of Yasmin® contains a combination of 3 mg of the progestin, drospirenone, and 0.03 mg of the estrogen, ethinyl estadiol.

37. Yaz® received approval from the FDA in 2006 and is essentially the same as Yasmin®, with the only difference being a slightly smaller amount of ethinyl estradiol.

38. Yasmin® and Yaz® were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

39. Yasmin® and Yaz® are indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.

40. Combination birth control pills are referred to as combined hormonal oral contraceptives.

41. Yasmin® and Yaz® contain a "Fourth Generation" progestin, drospirenone.

42. The estrogen component in Yasmin® and Yaz® is known as ethinyl estradiol.

43. Yasmin® contains 0.03 milligrams of ethinyl estradiol, and Yaz® contains 0.02 milligrams of ethinyl estradiol.

44. Both products contain 3 milligrams of drospirenone.

45. Yasmin® and Yaz® are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin®.

46. Drospirenone was not marketed in the United States prior to its use in Yasmin®.

47. Drospirenone is a diuretic and as such, creates unique risks as compared to other oral contraceptives and is known to cause problems with the gallbladder that may require surgical intervention.

48. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin® and Yaz® and significantly increased risk of gallbladder complications.

49. Yet, despite the wealth of scientific information available, Defendant ignored the correlation between the use of Yasmin® and Yaz® and the significantly increased risk of

gallbladder problems and still promoted, sold, advertised, and marketed the use of Yasmin® and Yaz® without sufficient warnings.

50. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

51. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g., lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes. The second generation progestins were considered safer for women to use.

52. During the 1990's, new "third generation" progestins were developed.

53. Unfortunately, these "third generation" progestins (e.g., gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

54. Yasmin® and Yaz® contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone.

55. On June 24, 2008, Barr Laboratories, Inc. ("Barr"), which is now a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva"), announced that it had entered into a supply and licensing agreement with the Bayer Defendants for the distribution of Ocella®, which is the generic version of Yasmin®. According to Bayer's *Press Release*, under the terms of that agreement, Bayer supplies Ocella® to Barr and Barr distributes Ocella® in the U.S. under the Barr Laboratories label.

56. According to IMS sales data, Ocella® had annual sales of approximately $170.2M in the United States for the twelve months ending December 31, 2008.

57. Since drospirenone is new, research data is not available to support its safe use. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

58. As a diuretic, drospirenone can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia (elevated blood potassium level).

59. Hyperkalemia can cause heart rhythm disturbances, such as extra systolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

60. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the legs where it can cause a deep vein thrombosis, or can travel to the brain causing stroke.

61. In addition, drospirenone can cause gallbladder disease and kidney stone formation which have been reported with the use of drospirenone in Yasmin®, Yaz®, and Ocella®. As a result, surgical intervention is often required.

62. Indeed, during the brief time that Yasmin® and Yaz® have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

63. In April 2002, THE BRITISH MEDICAL JOURNAL reported that the DUTCH COLLEGE OF GENERAL PRACTITIONERS recommended that older second generation birth control pills should be prescribed in lieu of Yasmin® as a result of 40 cases of venous thrombosis among women taking Yasmin®.

64. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin®* was published in the BRITISH MEDICAL JOURNAL, detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin® was suspected as the cause, including two deaths.

65. The FDA's adverse event data indicates staggering, serious adverse events that have been associated with Yasmin® and Yaz®, including but not limited to heart arrhythmias, electrolyte imbalance, hyponatremia, hyperkalemia, hyperkalemic arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, strokes, transient ischemic attacks, blood clot formation, gallbladder and kidney disease and/or sudden death.

66. In fact, from the first quarter of 2004 through the third quarter of 2008, the FDA received reports for more than 50 deaths where the decedents were users of Yasmin®, Yaz®, and Ocella®. Because of underreporting, the actual number of people who suffered side effects associated with these medications is actually 10 to 100 times more than reported.

67. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

68. Some deaths reported occurred in women as young as 17 years old.

69. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin®, Yaz®, or Ocella®.

70. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yasmin® or Yaz® over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that "oral contraceptives with . . . drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogesterel." Lidegard, et al., *Hormonal contraception and risk of venous thromboembolism: national follow up study,* THE BRITISH MEDICAL JOURNAL 2009, 330:B2921.

71. The second study found that Yasmin® or Yaz® users have twice the risk of a clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et al., *The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study*. THE BRITISH MEDICAL JOURNAL 2009, 339:B2921.

72. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the use of

Yasmin®, Yaz®, and Ocella®, but they have, through their marketing and advertising campaigns, urged women to use Yasmin®, Yaz® or Ocella® instead of birth control pills that present a safer alternative.

C. Over-Promotion of Yasmin® and Yaz®

73. Defendants market Yasmin® and Yaz® as effective for the treatment of premenstrual dysphoric disorder (hereinafter referred to as "PMDD"), premenstrual syndrome (hereinafter referred to as "PMS") and moderate acne, in addition to its FDA-approved use as an oral contraceptive.

74. Defendants market Yasmin® and Yaz® as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

75. Defendants market Yasmin® and Yaz® as lacking certain side-effects, such as weight gain, bloating, and water retention, common to many other oral contraceptives.

76. However, because Yasmin®, Yaz®, and Ocella® contain the fourth generation progestin drospirenone, which is a diuretic, these drugs present additional health risks not associated with other birth control pills.

77. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's® fourth generation progestin, drospirenone, by stating, "Ask about Yasmin®, and the difference a little chemistry can make."

78. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin® is superior to other COCs or that the

drospirenone in Yasmin® is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone[.]"

79. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

80. More recently, Defendants advertised that its product Yaz® was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

81. Defendants also advertised that Yaz® contained the added benefit of preventing or reducing acne.

82. In one of Defendants' commercials cited by the FDA, the song "*We're Not Gonna Take It*" plays in the background, while a series of young, fashionably dressed women kick away or puncture floating signs with labels saying "irritability" and "feeling anxious." Meanwhile, a voiceover promotes Yaz® as a "*pill that goes beyond the rest, with benefits like the ability to maintain clear skin."*

83. Another one of the Defendants' commercials is set to the tune of "*Goodbye to You*" and shows a variety of women next to balloons marked "*headaches," "acne"* and "*feeling anxious*", which float away, presumably after taking Yaz®.

84. In response to these ads, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz® for medical conditions beyond the limits of the FDA approval, and adding that "Yaz® has additional risks because it contains drospirenone … which

can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

85. The FDA further warned the Defendants that Yaz® "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

86. Indeed, the FDA felt Defendants' overpromotion of Yaz® was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz® advertisements regarding acne and premenstrual syndrome.

87. During 2008, when the ads in question were broadcast on television, Defendants' sales of Yaz® in the United States increased to approximately $616 million, from about $262 million in 2007. For 2008, Defendants' sales of Yasmin® totaled about $382 million, or about 11 percent of the United States market.

88. In February 2009, Bayer Corporation settled 27 claims with Attorneys General across the country, including Pennsylvania Attorney General, Thomas W. Corbett, Jr., for misleading marketing and sales practices of Yaz® and Yasmin®. The litigation alleged that Defendant Bayer Corporation overemphasized the benefits and minimized the risks of Yaz® and Yasmin®.

89. In response, Bayer Corporation acknowledged that it was the proper party to resolve claims relating to the sales and marketing of Yaz® and Yasmin® and the Consent Order clearly bears the signature of George J. Lykos, the Senior Vice President, Chief Legal Officer and Secretary of Bayer Corporation. Mr. Lykos is the only person who signed the consent judgment on behalf of Bayer Corporation. Bayer Corporation ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz® advertisements over the next six years to the FDA for advanced screening.

90. Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this complaint.

91. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of Yaz®, Yasmin® and Ocella® without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

92. As a result of Defendants' claim regarding the effectiveness and safety of Yaz®, Yasmin®, and Ocella®, Plaintiff's medical provider prescribed her and she ingested Yaz®.

D. Plaintiff's Use and Resulting Injuries

93. In or around October 6, 2008, after taking Yaz® as prescribed by her physician, Plaintiff required surgery to have her gallbladder removed.

94. As a direct and proximate result of using Yaz®, Plaintiff suffered the injuries described above.

95. Prior to Plaintiff's use of Yaz®, Defendants knew or should have known that the drug created a higher risk of gallbladder removal than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

96. Therefore, at the time Plaintiff used Yaz®, Defendants knew or should have known that the use of Yaz® created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

97. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz®, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

98. Had Plaintiff and/or her heath care providers known the risks and dangers associated with Yaz®, she would not have used Yaz® and would not have suffered the injuries described above.

99. As a direct and proximate result of her use of Yaz®, Plaintiff suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her gallbladder removal.

100. As a direct and proximate result of her use of Yaz®, Plaintiff has suffered and will continue to suffer pecuniary and other losses.

IV. CAUSES OF ACTION

COUNT I
FRAUDULENT CONCEALMENT

101. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

102. Prior to Plaintiff's use of Yaz® and during the period in which Plaintiff actually used Yaz®, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yaz®, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, deaths, cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, deep vein thrombosis and stroke. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in

other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Yaz® strong.

103. Defendants fraudulently concealed safety issues with Yaz® in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use Yaz®.

104. At the time Defendants concealed the fact that Yaz® was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Yaz®.

105. Plaintiff and Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of Yaz®.

106. As a direct and proximate result of Defendants' malicious and or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries.

107. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

108. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yaz® as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the Healthcare community and the general public. Without full knowledge of the dangers of Yaz®,

Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by Yaz® had a valid claim.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
STRICT LIABILITY

109. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

110. At the time of Plaintiff's injury, Defendants' pharmaceutical Yaz® was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

111. The Yaz® used by Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

112. Plaintiff did not misuse or materially alter the Yaz®.

113. Defendants are strictly liable for Plaintiff's injury in the following ways:

a. The pharmaceutical Yaz® as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell Yaz®;

c. Defendants failed to warn and/or place adequate warnings and instructions on Yaz®;

d. Defendants failed to adequately test Yaz®;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Yaz®; and

f. A feasible alternative design existed that was capable of preventing Plaintiff's injury.

114. Defendants' actions and omissions were the direct and proximate cause of Plaintiff's injury.

115. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

116. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

117. At the time Defendants marketed, distributed and sold Yaz® to Plaintiff, Defendants warranted that the drugs were merchantable and fit for the ordinary purposes for which they were intended.

118. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

119. Yaz® was not merchantable and fit for its ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this complaint.

120. Plaintiff reasonably relied on Defendants' representations that Yaz® was safe and free of defects and was a safe means of birth control.

121. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injury.

122. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

123. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

124. Defendants sold Yaz® with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

125. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

126. Yaz® was not fit for the particular purpose of a safe birth control pill without serious risk of personal injury, which risk is much higher than other birth control pills.

127. Plaintiff reasonably relied on Defendants' representations that Yaz® was safe and effective for use as a birth control method.

128. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiff's injury.

129. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their product, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT FAILURE TO WARN

130. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

131. Before Plaintiff used Yaz®, and during the period in which she used the drug, Defendants knew or had reason to know that Yaz® was dangerous and created an unreasonable risk of bodily harm to consumers.

132. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Yaz® likely to be dangerous.

133. Despite the fact that Defendants knew or had reason to know that Yaz® was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Yaz® likely to be dangerous.

134. Plaintiff's injury was a direct and proximate result of Defendants' failure to warn of the dangers of Yaz®.

135. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE

136. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

137. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of Yaz®, including a duty to assure that the products did not cause unreasonable, dangerous side effects to users.

138. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of Yaz® in that the Defendants knew or should have known that the drug created a high risk of unreasonable harm.

139. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Yaz® in that, among other things, they:

a. Failed to use due care in designing and manufacturing Yaz® so as to avoid the aforementioned risks to individuals;

b. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of Yaz®;

d. Placed unsafe products into the stream of commerce; and

e. Were otherwise careless or negligent.

140. Despite the fact that Defendants knew or should have known that Yaz® caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market the drugs to consumers, including the medical community and Plaintiff.

141. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

142. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

143. Prior to Plaintiff first using Yaz®, and during the period in which she used Yaz®, Defendants misrepresented that Yaz® was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of Yaz®, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life threatening.

144. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

145. Defendants knew or should have known, based on their prior experience, adverse event reports, and studies and knowledge of the efficacy and safety failures with Yaz®, that their

representations regarding Yaz® were false, and that they had a duty to disclose the dangers of Yaz®.

146. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing Yaz®.

147. Plaintiff justifiably relied on Defendants' representations and nondisclosures by purchasing and using Yaz®.

148. Defendants' misrepresentations and omissions regarding the safety and efficacy of Yaz® were the direct and proximate cause of Plaintiff's injuries.

149. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

150. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

151. Defendants expressly warranted that Yaz® was safe and effective to members of the consuming public, including Plaintiff.

152. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

153. Defendants marketed, promoted and sold Yaz® as a safe method of birth control.

154. Yaz® does not conform to these express representations because it is not safe and has serious side effects, including death.

155. Defendants breached their express warranty in one or more of the following ways:

a. Yaz® as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on Yaz®;

c. Defendants failed to adequately test Yaz®; and

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Yaz®.

156. Plaintiff reasonably relied upon Defendants' warranty that Yaz® was safe and effective when she purchased and used the medications.

157. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

158. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the

unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
FRAUD

159. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

160. Defendants widely advertised and promoted Yaz® as safe and effective medications.

161. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

162. Additionally, by virtue of Defendants' partial disclosures about the medications, in which Defendants touted Yaz® as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

163. Had Plaintiff been aware of the hazards associated with Yaz®, Plaintiff would not have consumed the products that led proximately to Plaintiff's adverse health effects.

164. Defendants' advertisements regarding Yaz® made material misrepresentations to the effect that Yaz® was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to

purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and consume Yaz®.

165. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Yaz® with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
VIOLATION OF DECEPTIVE TRADE PRACTICES ACT

166. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceeding paragraphs and further alleges on information and belief as follows:

167. Defendants violated the Deceptive Trade Practices Act ("DTPA") of the state in which Plaintiff resides by use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion and sale of Yaz®.

168. Defendants communicated the purported benefits of Yaz® while failing to disclose the serious and dangerous side effects related to the use of Yaz® with the intent that consumers, like Plaintiff, and her health care providers, rely upon the omissions and misrepresentations and purchase or prescribe Yaz®.

169. As a result of violating the DTPA, Defendants caused Plaintiff to be prescribed and to use Yaz®, causing severe injuries and damages as described herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
LOSS OF CONSORTIUM

170. Plaintiff incorporates by reference all preceeding paragraphs as if fully set forth herein.

171. Plaintiff Michael Hemmitt was at all times relevant hereto the spouse of Plaintiff, and lived and cohabited with her.

172. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to personal injuries, medical expenses, and pain and suffering sustained by Plaintiff, Plaintiff Michael Hemmitt suffered the loss of companionship, society, services, and consortium of his wife.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $350,000.00;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Attorneys' fees, expenses, and costs of this action;

4. Punitive damages in excess of twice the compensatory damages award;

5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all triable issues.

Respectfully submitted,

SEEGER WEISS LLP

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Date: September 29, 2010